

Final Belgian list: (Last update 18/11/2013)

marketing name	Active substance	MAH	Reason on list
ADCETRIS	BRENTUXIMAB VEDOTINE	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS, Cond Auth, PASS
ALDURAZYME	LARONIDASE	GENZYME EUROPE B.V.	Auth under excep circumstances, PASS
AMYVID	FORBETAPIR (F-18) Q.S.	ELI LILLY NEDERLAND BV	New AS
ARZERRA	OFATUMUMAB 20.00 MG/ML	GLAXO GROUP LTD	Conditional auth, PASS
ATRIANCE	NELARABINE 5.00 MG/ML	GLAXO GROUP LTD	Auth under excep circumstances
ATRYN	ANTITHROMBIN ALFA	GTC BIOTHERAPEUTICS UK LIMITED	Auth under excep circumstances, PASS
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS
BETMIGA	MIRABEGRON	ASTELLAS PHARMA EUROPE B.V.	New AS
BEXSERO	NEISSERIA MENINGITIDES B, RECOMBINANT, COMPONENT, ADSORBED Q.S.	NOVARTIS VACCINES & DIAGNOSTICS S.R.L.	New AS
BINDREN	COLESTILAN	NOVARTIS VACCINES & DIAGNOSTICS S.R.L.	New AS
BOSULIF	BOSUTINIB (MONOHYDRATE) 100.00 MG	PFIZER LIMITED	New AS, Cond Auth, PASS
BRETARIS GENUAIR	ACLIDINIUM (BROMURE)	ALMIRALL S.A	New AS, PASS
CAPRELSA	VANDETANIB	ASTRAZENECA AB	New AS, Cond Auth
CEPLENE	HISTAMINE DIHYDROCHLORIDE	MEDA AB	Auth under excep circumstances
CHAMPIX	VARENICLINE (TARTRATE)	PFIZER LIMITED	PASS
CHLOE	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	MITHRA PHARMACEUTICALS S.A.	PASS
CINRYZE	C1-INHIBITOR 500.00 IU	VIOPHARMA BVBA	PASS
CLAUDIA - 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	SANDOZ N.V.	PASS
CLEVIPREX	CLEVIDIPINE BUTYRATE	THE MEDICINES COMPANY UK LTD	New AS
CONSTELLA	LINACLOTIDE	ALMIRALL S.A	New AS
CUPRYMINA	COPPER (64-CU) CHLORIDE Q.S.	SPARKLE S.R.L	New AS
DACOGEN	DECITABINE	JANSSEN-CILAG INTERNATIONAL NV	New AS
DALIRESP	ROFLUMILAST 500.00 MCG	NYCOMED GMBH	PASS
DAPHNE	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	MITHRA PHARMACEUTICALS S.A.	PASS
DAXAS	ROFLUMILAST	NYCOMED GMBH	PASS
DEFITELIO	DEFIBROTIDE	???	New biological, authorised under exceptional circumstances
DIACOMIT	STIRIPENTOL	BIOCODEX	Conditional auth
DIANE-35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	BAYER N.V.	PASS
DIFICLIR	FIDAXOMICIN	ASTELLAS PHARMA EUROPE B.V.	New AS

EDARBI	AZILSARTAN MEDOXOMIL (POTASSIUM)	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS
EDURANT	RILPIVIRINE (HYDROCHLORIDE)	JANSSEN-CILAG INTERNATIONAL NV	New AS
EKISTOL	CILOSTAZOL	???	Outcome Referral Art 31, PASS
EKLIRA GENUAIR	ACLIDINIUM (BROMURE)	ALMIRALL S.A.	New AS, PASS
ELAPRASE	IDURSULFASE	SHIRE HUMAN GENETIC THERAPIES AB	Auth under excep circumstances
ELIQUIS	APIXABAN	BRISTOL MYERS SQUIBB/PFIZER EEIG	New AS
ELISAMYLAN 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	MYLAN BVBA/SPRL	PASS
ELVANSE / TYVENSE	LISDEXAMPHETAMINE	BRYSTOL MYERS SQUIBB/ PFIZER EEIG	New AS
ENUREV BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS
ERIVEDGE	VISMODEGIB	ROCHE REGISTRATION LIMITED	New AS, Cond Auth
ESBRIET	PIRFENIDONE	INTERMUNE EUROPE LTD	New AS, PASS
EURARTESIM	PIPERAQUINE TETRAPHOSPHATE (TETRAHYDRATE) , DIHYDROARTEMISININ (DHA)	SIGMA-TAU INDUSTRIE FARMAC. RIUNITE SPA	New AS, PASS
EVARREST	FIBRINOGEN, HUMAN Q.S., THROMBIN, HUMAN Q.S.	OMRIX BIOPHARMACEUTICALS N.V.	New Biological
EVIPLERA	ENOFOVIR DISOPROXIL (FUMARATE) , EMTRICITABINE , RILPIVIRINE (HYDROCHLORIDE)	GILEAD SCIENCES LTD	New AS
EVOLTRA	CLOFARABINE	GENZYME EUROPE B.V.	Auth under excep circumstances
EXJADE	DEFERASIROX	NOVARTIS EUROPHARM LIMITED	PASS
EYLEA	AFLIBERCEPT	BAYER AG	New AS
FAMPYRA	FAMPRIDINE	BIOGEN IDEC LTD	New AS, Cond Auth
FIRDAPSE	AMIFAMPRIDINE (PHOSPHATE)	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
FLUENZ	INFLUENZA VIRUS, LIVE, ATTENUATED Q.S.	MEDIMMUNE LLC	New AS
FORXIGA	DAPAGLIFLOZIN (PROPANEDIOL MONOHYDRATE)	BRISTOL MYERS SQUIBB/ASTRAZENECA EEIG	New AS
FYCOMPA	PERAMPANEL	EISAI EUROPE LTD	New AS
GILENYA	FINGOLIMOD (HYDROCHLORIDE) 0.50 MG	NOVARTIS EUROPHARM LIMITED	New AS, PASS
GIOTRIF	AFATINIB	???	New AS
GLYBERA	ALIPOGENE TIPARVOVEC Q.S.	UNIQUIRE BIOPHARMA B.V	New AS, Auth under excep circumstances, PASS
GRASTOFIL	FILGASTRIM	???	New Biological
GRATIELLA 35	ETHINYLESTRADIOL 35.00 MCG, CYPROTERONE ACETATE 2.00 MG	3DDD PHARMA N.V.	PASS
HALAVEN	ERIBULIN (MESYLATE) 0.44 MG/ML	EISAI LIMITED	New AS

HEXACIMA	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rdNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOFI PASTEUR SA	New Biological
HEXYON	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rdNA), poliomyelitis (inactivated) and Haemophilus influenzae type B conjugate vaccine (adsorbed)	SANOFI PASTEUR MSD	New Biological
HIZENTRA	IMMUNOGLOBULIN HUMAN NORMAL 200.00 MG/ML	BIOCLS GMBH	New Biological
HYQVIA	IMMUNOGLOBULIN HUMAN NORMAL 100.00 MG/ML	BAXTER INNOVATIONS GMBH	New Biological
ICLUSIG	PONATINIB (HYDROCHLORIDE)	ARIAD PHARMA LTD	New AS
ILARIS	CANAKINUMAB	NOVARTIS EUROPHARM LIMITED	Auth under excep circumstances, PASS
IMVANEX	Modi fi ed Vaccini a Ankara virus - Bavarian Nordic (MVA-BN) live virus	BAVARIAN NORDIC A/S	New AS, Auth under excep circumstances
INCIVO	TELAPREVIR	JANSSEN-CILAG INTERNATIONAL NV	New AS
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS
INCRESYNC	Alogliptin/pioglitazone	???	New AS
INFLECTRA	NFLIXIMAB	HOSPIRA UK LTD	New Biological
INFLUSPLIT TETRA	Influenza virus inactivated split virion	GLAXO GROUP LTD	Biological
INLYTA	AXITINIB	PFIZER LIMITED	New AS
INTELENCE	ETRAVIRINE	JANSSEN-CILAG INTERNATIONAL NV	Conditional auth
INVIRASE	SAQUINAVIR (MESILATE)	ROCHE REGISTRATION LIMITED	PASS
IPREZIV	AZILSARTAN MEDOXOMIL (POTASSIUM)	TAKEDA GLOBAL R&D CENTRE (EUROPE) LTD	New AS
JAKAVI	RUXOLITINIB (PHOSPHATE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS
JENTADUETO	METFORMIN HYDROCHLORIDE , LINAGLIPTIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
JETREA	OCRIPLASMIN	THROMBOGENICS NV	New AS
JEVTANA	CABAZITAXEL	SANOFI-AVENTIS GROUPE	New AS
KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS LIMIT	New AS, PASS
KRYSTEXXA	PEGLOTICASE	SAVIENT PHARMA IRELAND LIMITED	New AS, PASS
LACTEST	GASIOXE	Lactest S.L. / Venter Pharma S.L.	New AS
LEMTRADA	ALEMTUZUMAB	GENZYME THERAPEUTICS LTD	New Biological
LIBERTEK	ROFLUMILAST	NYCOMED GMBH	PASS
LOJUXTA	LOMITAPIDE (MESYLATE)	AEGERION PHARMACEUTICALS	New AS, Auth under excep circumstances

LONQUEX	LIPEGFILGRASTIM	TEVA PHARMA BV	New AS, PASS
LYXUMIA	LIXISENATIDE	SANOFI-AVENTIS GROUPE	New AS
MACI	CHONDROCYTES, AUTOLOGOUS CULTURED Q.S.	GENZYME EUROPE B.V.	New AS
NAGLAZYME	GALSULFASE	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
NEXOBRID	PROTEOLYTIC ENZYMES (CONCENTRATE) ENRICHED IN BROMELAIN	TEVA PHARMA GMBH	New AS, PASS
NIMENRIX	NEISSERIA MENINGITIDES A+C+W+Y, POLYSACCHARIDE CONJ. TO TETANUS TOXOID Q.S.	GLAXOSMITHKLINE BIOLOGICALS S.A.	New AS, PASS
NOVOTHIRTEEN	CATRIDECACOG	NOVO NORDISK A/S	New AS
NULOJIX	BELATACEPT	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
OPGENRA	EPTOTERMIN ALFA	OLYMPUS BIOTECH LTD	PASS
OPTIMARK	GADOVERSETAMIDE	MALLINCKRODT MEDICAL GMBH	PASS
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances
OSSEOR	STRONTIUM RANELATE	SERVIER, LES LABORATOIRES	PASS
OVALEAP	FOLLITROPIN ALPHA	???	New Biological
PANDEMRIX	INFLUENZA VIRUS (INACTIVATED) Q.S.	GLAXOSMITHKLINE BIOLOGICALS S.A.	PASS
PERJETA	PERTUZUMAB	ROCHE REGISTRATION LIMITED	New AS
PICATO	INGENOL MEBUTATE	LEO PHARMA A/S	New AS
PIXUVRI	PIXANTRONE (DIMALEATE)	CTI LIFE SCIENCES LTD	New AS, Cond Auth
PLETAL	CILOSTAZOL	???	Outcome Referral Art 31, PASS
POMALIDOMIDE CELGENE	POMALIDOMIDE	CELGENE EUROPE LIMITED	New AS, PASS
PRIALT	ZICONOTIDE (ACETATE)	EISAI LIMITED	Auth under excep circumstances, PASS
PROTELOS	STRONTIUM RANELATE	SERVIER, LES LABORATOIRES	PASS
PROVENGE	AUTOLOGOUS PERIPHERAL BLOOD MONONUCLEAR CELLS ACTIVATED WITH PAP-GM-CS Q.S.	DENDREON UK LIMITED	New AS, PASS
REMSIMA	INFLIXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
REPLAGAL	AGALSIDASE ALFA	SHIRE HUMAN GENETIC THERAPIES AB	Auth under excep circumstances, PASS
REVESTIVE	TEDUGLUTIDE	NYCOMED DANMARK APS	New AS, PASS
RIENSO	FERUMOXYTOL	TAKEDA PHARMA A/S	New AS
RYZODEG	INSULIN ASPART 30.00 UML, INSULIN DEGLUDEC 70.00 UML	NOVO NORDISK A/S	New AS
SEEBRI BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS
SELINCRO	NALMEFENE (HYDROCHLORIDE DIHYDRATE)	LUNDBECK A/S	New AS

SIGNIFOR	PASIREOTIDE (DIASPARTATE)	NOVARTIS EUROPHARM LIMITED	New AS
SOMATROPIN BIOPARTNERS	SOMATROPIN	BIOPARTNERS	New Biological
SPEDRA	AVANAFIL	VIVUS BV	New AS
STIVARGA	REGORAFENIB	BAYER AG	New AS
STRIBILD	TENOFOVIR DISOPROXIL (FUMARATE) , EMTRICITABINE , ELVITEGRAVIR , COBICISTAT	GILEAD SCIENCES LTD	New AS
TAFINLAR	DABRAFENIB	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS
TEYSUNO	TEGAFUR , GIMERACIL , OTERACIL (MONOPOTASSIUM)	NORDIC GROUP BV	New AS, PASS
TOVANOR BREEZHALER	GLYCOPYRRONIUM (BROMIDE)	NOVARTIS EUROPHARM LIMITED	New AS, PASS
TRAJENTA	LINAGLIPTIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
TRESIBA	INSULIN DEGLUDEC	NOVO NORDISK A/S	New AS
TROBALT	RETIGABINE	GLAXO GROUP LTD	New AS
TYBOST	COBICISTAT	???	New AS
TYGACIL	TIGECYCLINE	PFIZER LIMITED	PASS
TYSABRI	NATALIZUMAB	BIOGEN IDEC LTD	PASS
TYVERB	LAPATINIB (DITOSYLATE MONOHYDRATE)	GLAXO GROUP LTD	Conditional auth
ULTIBRO BREEZHALER	INDACATEROL (MALEATE) 85.00 MCG/DO, GLYCOPYRRONIUM (BROMIDE) 43.00 MCG/DO	NOVARTIS EUROPHARM LIMITED	PASS
VECTIBIX	PANITUMUMAB 20.00 MG/ML	AMGEN EUROPE BV	Conditional auth
VEDROP	TOCOPHEROL D-ALPHA (AS TOCOFERSOLAN)	ORPHAN EUROPE SARL	Auth under excep circumstances, PASS
VEPACEL	INFLUENZA VIRUS (INACTIVATED) Q.S.	BAXTER INNOVATIONS GMBH	New AS
VICTRELIS	BOCEPREVIR	MERCK SHARP & DOHME LTD	New AS
VIPDOMET	ALOGLYPTIN / METFORMIN	???	New AS
VIPIDIA	ALOGLYPTIN	???	New AS
VONCENTO	FACTOR VIII HUMAN 1000.00 IU, FACTOR VON WILLEBRAND 2400.00 IU	TEVA PHARMA BV	New Biological
VOTUBIA	EVEROLIMUS	NOVARTIS EUROPHARM LIMITED	Conditional auth
VYNDAQEL	TAFAMIDIS (MEGLUMINE)	PFIZER LIMITED	Auth under excep circumstances, New AS, PASS
XAGRID	XAGRID	SHIRE PHARMACEUTICAL CONTRACTS LTD	Auth under excep circumstances
XALKORI	CRIZOTINIB	PFIZER LIMITED	New AS, Cond Auth
XARELTO	RIVAROXABAN 10.00 MG	BAYER SCHERING PHARMA AG	PASS
XGEVA	DENOSUMAB	AMGEN EUROPE BV	New biological
XIAPEX	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	AUXILIUM UK LIMITED	New AS

XOTERNA BREEZHALER	INDACATEROL / GLYCOPYRRONIUM	TEVA PHARMA BV	PASS
XTANDI	ENZALUTAMIDE	ASTELLAS PHARMA EUROPE B.V.	New AS
YELLOX	BROMFENAC (SODIUM SESQUIHYDRATE)	CROMA-PHARMA GMBH	New AS
YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS, PASS
YONDELIS	TRABECTEDIN	PHARMA MAR SA	Auth under excep circumstances
ZALTRAP	AFLIBERCEPT	SANOFI-AVENTIS GROUPE	New AS
ZELBORAF	VEMURAFENIB	ROCHE REGISTRATION LIMITED	New AS
ZINFORO	CEFTAROLINE FOSAMIL (ACETIC ACID SOLVATE MONOHYDRATE)	ASTRAZENECA AB	New AS
ZYTIGA	ABIRATERONE ACETATE	JANSSEN-CILAG INTERNATIONAL NV	New AS

NOTE	
In Red	commercialised / commercialisé / gecommmercialiseerd
in Black	not commercialised / pas commercialisé / niet gecommmercialiseerd
in blue	info not yet available / info non disponible / info niet beschikbaar
in grey	New addition of this month / nouvelle addition de ce mois / nieuwe toevoeging van deze maand
New AS	nouvelle substance active / nieuw actief bestanddeel
New Biological	nouveau médicament biologique / nieuwe biologische geneesmiddel
PASS	Etude de sécurité post-autorisation / post-autorisatie veiligheidsstudies
Conditional auth	Autorisé sous certaines conditions / vergund onder bepaalde voorwaarden
Auth under excep circumstances	autorisé sous circonstances exceptionnelles / vergund onder uitzonderlijke omstandigheden

Product informations / in informations sur les produits/productinformatie

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